Effective Date: 08/09/2018

Intravitreal Injections for Retinal Conditions
Eylea™ (afiblercept)
Lucentis® (ranibizumab)
Macugen® (pegaptanib)

FDA approval: Various
HCPCS: Lucentis – J2778; Eylea – J0178; Macugen – J2503
Benefit: Medical

Policy/Criteria:

Note: Requests must be supported by submission of chart notes and patient specific documentation.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eylea™: (afiblercept)</td>
<td>1. Prescribed by an ophthalmologist AND 2. Diagnosis of neovascular (wet) age related macular degeneration (AMD) OR 3. Diagnosis of macular edema due to retinal vein occlusion (RVO) OR 4. Diagnosis of diabetic macular edema (DME) OR 5. Diabetic retinopathy (DR) in patients with DME AND 6. Treatment with bevacizumab AND a preferred intravitreal anti-VEGF has been ineffective, not tolerated or contraindicated</td>
</tr>
</tbody>
</table>

Quantity Limitations and Authorization Period
1. Initial authorization period: 1 year
2. Wet AMD: 2 mg administered via intravitreal injection every 4 weeks for the first 12 weeks, followed by 2 mg every 8 weeks
3. Macular edema due to Retinal Vein Occlusion: 2 mg monthly
4. DME & DR: 2mg administered via intravitreal injection every 4 weeks for the first 5 injections, followed by 2mg every 8 weeks
5. Authorization may be reviewed at least annually to confirm maintenance or improvement of visual acuity [e.g., stabilization or gain of Snellen and/or ETDRS letters; stabilization or gain of ETDRS-DRSS score]

| Lucentis®: (ranibizumab) | 1. Prescribed by an ophthalmologist AND 2. Diagnosis of neovascular (wet) age related macular degeneration( AMD) OR |

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3. Diagnosis of macular edema due to retinal vein occlusion (RVO) 
OR
4. Diagnosis of diabetic macular edema (DME) 
OR
5. Diabetic retinopathy (DR) 
OR
6. Myopic choroidal neovascularization (mCNV) 
AND
7. Treatment with bevacizumab AND a preferred intravitreal anti-VEGF has been ineffective, not tolerated or contraindicated

Quantity Limitations and Authorization Period
1. Initial authorization period: 1 year
2. Macular edema due to RVO/AMD: 0.5 mg administered via intravitreal injection every 4 weeks.
3. DME & DR: 0.3 mg administered via intravitreal injection every 4 weeks.
4. mCNV: 0.5 mg administered via intravitreal injection every 4 weeks for up to three months.
5. Authorization may be reviewed at least annually to confirm maintenance or improvement of visual acuity [e.g., stabilization or gain of Snellen and/or ETDRS letters; stabilization or gain of ETDRS-DRSS score]

Macugen®: (pegaptinib)
1. Prescribed by an ophthalmologist 
AND
2. Diagnosis of neovascular (wet) age related macular degeneration (AMD) 
AND
3. Treatment with bevacizumab AND a preferred intravitreal anti-VEGF has been ineffective, not tolerated or contraindicated 

Quantity Limitations and Authorization Period
1. Initial authorization period: 1 year
2. 0.3 mg administered via intravitreal injection once every 6 weeks.
3. Authorization may be reviewed at least annually to confirm maintenance or improvement of visual acuity [e.g., stabilization or gain of Snellen or ETDRS letters]

*ETDRS: Early Treatment Diabetic Retinopathy Study; ETDRS-DRSS: Early Treatment Diabetic Retinopathy Study Diabetic Retinopathy Severity Scale

- Eylea, Lucentis, and Macugen are considered investigational when used for all other conditions, including but not limited to:
  a) Used in combination with other intravitreal VEGF inhibitors
  b) Choroidal retinal neovascularization, secondary to pathologic myopia (Lucentis)
  c) Diabetic macular edema (DME) (Macugen)

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia

Therapeutic considerations:

A. FDA approved indication / Diagnosis
B. 

| Eylea | Lucentis | Macugen |

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determinations.

<table>
<thead>
<tr>
<th>Neovascular (wet) Age-Related Macular Degeneration (AMD)</th>
<th>X</th>
<th>X</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Macular Edema Following Retinal Vein Occlusion</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Diabetic Macular Edema (DME)</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Diabetic Retinopathy</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Myopic choroidal neovascularization (mCNV)</td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

*Please refer to most recent prescribing information.

C. Background Information
a. The use of intravitreal injections technique has been widely used by ophthalmologists to treat various ocular
diseases; the diseases include but are not limited to: neovascular age related macular degeneration, diabetic
macular edema, and macular edema due to retinal vein occlusions. This procedure, which consists of injecting
the drug directly into the center of the eye, can be done in the outpatient setting with the use of local anesthetics;
hospitalization is not necessary.
b. The current intravitreal anti-VEGFs on the market include: aflibercept, bevacizumab, pegaptinib, and
ranibizumab. These drugs work by binding to the growth factors to suppress the formation of irregular blood
vessels. Bevacizumab is the best value VEGF inhibitor for the treatment of ocular conditions.

D. Efficacy

*Please refer to most recent prescribing information.

E. Medication Safety Considerations

Black Box Warning: No

*Please refer to most recent prescribing information.

F. Dosing and administration

<table>
<thead>
<tr>
<th>Neovascular (wet) Age-Related Macular Degeneration (AMD)</th>
<th>Eylea</th>
<th>Lucentis</th>
<th>Macugen</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 2mg every 4 weeks for 12 weeks, THEN</td>
<td>• 0.5mg every 4 weeks</td>
<td>• 2mg every 6 weeks</td>
<td></td>
</tr>
<tr>
<td>• 2mg every 8 weeks thereafter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Macular Edema Following Retinal Vein Occlusion (RVO)</td>
<td>• 2mg monthly</td>
<td>• 0.5mg every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Diabetic Macular Edema (DME)</td>
<td>• 2mg every 4 weeks x 5 injections, THEN 2mg every 8 weeks thereafter</td>
<td>• 0.3mg every 4 weeks</td>
<td>N/A</td>
</tr>
<tr>
<td>Diabetic Retinopathy</td>
<td>• 2mg every 4 weeks x 5 injections, THEN 2mg every 8 weeks</td>
<td>• 0.3mg every 4 weeks</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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**Table:**

<table>
<thead>
<tr>
<th>Myopic choroidal neovascularization (mCNV)</th>
<th>N/A</th>
<th>0.5mg every 4 weeks</th>
<th>N/A</th>
</tr>
</thead>
</table>

*Please refer to most recent prescribing information.

**G. How supplied**

*Please refer to most recent prescribing information

**References:**

5. Blue Cross Blue Shield association : Medical Policy: Visudyne® (Verteporfin)
6. Blue Cross Blue Shield Association : Pharmacy and Therapeutic Committee on July 15, 2010: Avastin
7. Lucentis [prescribing information]. South San Francisco, CA Genentech, Inc; April 2017.

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## Policy History

<table>
<thead>
<tr>
<th>#</th>
<th>Date</th>
<th>Change Description</th>
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</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Effective Date: 11/08/12</td>
<td>New Policy (refer to cross references above)</td>
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<tr>
<td>1.1</td>
<td>Effective Date: 5/8/14</td>
<td>Yearly update.</td>
</tr>
<tr>
<td>1.2</td>
<td>Effective Date: 5/7/15</td>
<td>Updated policy to reflect new Lucentis indication (DR) &amp; updated template</td>
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<tr>
<td>1.3</td>
<td>Effective Date: 8/13/15</td>
<td>Updated policy to reflect new Eylea indication (DR) &amp; updated renewal criteria</td>
</tr>
<tr>
<td>1.4</td>
<td>Effective Date: 02/09/2017</td>
<td>Annual Review; No criteria changes. Updated template.</td>
</tr>
<tr>
<td>1.5</td>
<td>Effective Date: 08/08/2017</td>
<td>Updated policy to reflect new Lucentis indication (mCNV) AND (DR)</td>
</tr>
<tr>
<td>1.6</td>
<td>Effective Date: 08/08/2018</td>
<td>Annual Review of Medical Policy</td>
</tr>
</tbody>
</table>

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm)